DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

August 7, 2014

Hansen Medical
Kate Whitin
Sr. Director, Regulatory Affairs
800 East Middlefield Road
Mountain View, California 94043

Re: K141614
Trade/Device Name: Magellan Robotic System
Regulation Number: 21 CFR 870.1290
Regulation Name: Steerable Catheter Control System
Regulatory Class: Class II
Product Code: DXX
Dated: June 12, 2014
Received: June 16, 2014

Dear Ms. Whitin:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

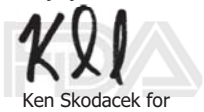
Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical

device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,



Ken Skodacek for
Bram D. Zuckerman, M.D.
Director
Division of Cardiovascular Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

SECTION 6

Indications for Use

510(k) Number (if known): K141614

Device Name: Hansen Medical Magellan Robotic System and accessory components

Indications for Use:

The Hansen Medical Magellan Robotic System and accessory components are intended to be used to facilitate navigation to anatomical targets in the peripheral vasculature and subsequently provide a conduit for manual placement of therapeutic devices.

The Magellan Robotic System is intended to be used with compatible Hansen Medical robotically steerable catheters.

Prescription Use _x_ (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use _____ (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE OF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Ken Skodacek for

Bram Zuckerman

SECTION 7

510(k) SUMMARY

This summary of 510(k) safety and effectiveness information is submitted in accordance with the requirements of 21 CFR 807.92(c).

510(k) Number: **K141614**

Applicant Information:

Owner Name:	Hansen Medical, Inc.
Address:	800 East Middlefield Road Mountain View, CA. 94043 Office: 650-404-5800
Establishment Registration Number:	3006026430
Contact Person:	Kate Whitin Lee
Phone Number:	650 404 5841
Facsimile Number:	650 404 2773
Date Prepared:	August 5, 2014

Device Information:

Regulatory Class:	Class II
Trade/Device Name:	Hansen Medical Magellan Robotic System and Accessory Components
Common name:	Steerable Catheter Control System
Classification name:	System, Catheter Control, Steerable
Regulation number:	21 CFR 870.1290
Product Code:	DXX

Predicate Device:

The modified Hansen Medical Magellan System (Magellan Robotic System), is substantially equivalent in intended use and method of operation to the cleared Magellan System (Magellan Robotic System) cleared under K132369.

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Device Description:

The Hansen Medical Magellan Robotic System and accessory components are designed to facilitate navigation to anatomical targets in the peripheral vasculature and subsequently provide a conduit for manual placement of therapeutic devices. The fundamental concept of the system is based on a master/slave control system that enables and visualizes positioning of a steerable catheter tip at a desired point inside the vasculature, while enabling a physician to remain seated and away from the x-ray radiation source. The modification adds a mechanical joint between the Magellan Robotic System Rail and Adapter Plate to facilitate removal.

The Magellan Robotic System and accessory components are compatible with Hansen Medical robotically steerable catheters approved under previous 510(k)s.

Intended Use:

The Hansen Medical Magellan Robotic System and accessory components are intended to be used to facilitate navigation to anatomical targets in the peripheral vasculature and subsequently provide a conduit for manual placement of therapeutic devices.

The Magellan Robotic System is intended to be used with compatible Hansen Medical robotically steerable catheters.

Comparison to Predicate Device(s):

The Magellan Robotic System and accessory components are substantially equivalent to the predicate device. The modifications described herein do not affect the intended use of the device or alter the fundamental scientific technology associated with the device. Both the proposed and predicate device facilitate navigation to anatomical targets in the peripheral vasculature and subsequently provide a conduit for manual placement of therapeutic devices, while allowing the physician to perform the procedure from a position beyond the radiation field.

Technological Characteristics/Performance Data:

The Magellan Robotic System and accessory components are substantially equivalent to the predicate device in intended use, fundamental scientific technology, and performance specifications. Design verification testing was

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performed to verify that the performance of the Magellan Robotic System remains substantially equivalent to the predicate device. Testing performed on the Magellan Robotic System included the following:

- Visual and Dimensional Verification Testing
- IEC 606061-1 Testing
- Table Compatibility
- Life cycle Testing

All of the pre-determined acceptance criteria were met.

Clinical Testing:

No additional clinical evaluation of the Magellan Robotic System is required as a result of these changes.

Substantial Equivalence:

The Magellan Robotic System has the following similarities to the predicate device cleared under K132369:

- has the same intended use, although the indications for use are limited to the robotic system and accessory components,
- has the same fundamental scientific technology,
- has the same technological characteristics, and
- has the same principles of operation.

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Summary:

In summary, the Magellan Robotic System and accessory components subject to this submission are as safe and effective as the predicate device. They have the same intended use, the same fundamental technological characteristics, and the same principles of operation as the predicate device. The differences between the Magellan Robotic System and the predicate device raise no new issues of safety or effectiveness. Performance data demonstrate that the Magellan Robotic System and accessory components are as safe and effective as the predicate device and are therefore substantially equivalent.

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